



# CLIA BITS



North Dakota Department of Health  
Division of Health Facilities

Spring 2002

## Take Time To Celebrate

National Medical Laboratory Week 2002 will be held April 14-20, 2002. This year's theme is *Laboratory Professionals: Quality Care Through Quality Testing*. NMLW recognizes the vital role laboratorians play in every aspect of health care. You are important! Take time to celebrate the difference you make.



## CLIA Proposed Rule Published

On Dec. 28, 2001, the proposed rule entitled "Medicare, Medicaid, and CLIA Programs; Qualification Requirements for Directors of Laboratories Performing High Complexity Testing," CMS-2094-P, was published in the Federal Register. This proposed rule would revise and expand the qualification requirements by which an individual who has a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing. The proposed change provides three alternatives

for an individual to meet in order to be qualified to serve as a director of a laboratory that performs high complexity testing. The person must hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and either:

- On or after Jan. 1, 2003, be certified and continue to be certified by an HHS-approved board;
- Before Jan. 1, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least two years of laboratory training or experience (or both) and two years of experience directing or supervising high complexity testing; or
- Have at least six years of laboratory training or experience, or both; including two years of experience directing or supervising high complexity testing.

The comment period to this proposed rule ended Jan. 28, 2002. It may be viewed at: [www.phppo.cdc.gov/clia/pdf/fr28de01p.pdf](http://www.phppo.cdc.gov/clia/pdf/fr28de01p.pdf).

## Stark II Regulation

On Dec. 3, 2001, the Centers for Medicare and Medicaid Services (CMS) issued a notice delaying one aspect of the final Stark II regulation released Jan. 4, 2001. The Stark II final rule makes it illegal for a physician to

make referrals to an entity with which he/she has a financial relationship, but provides certain exceptions. CMS is delaying the interpretation set on Jan. 4, 2001, of the term "set in advance" when referring to compensation arrangements. The delay is until Jan. 6, 2003, and is intended to relieve providers and physicians of the task of renegotiating a host of contracts that include certain percentage compensation plans which are excluded in the new definition of "set in advance." The remaining provisions of the Stark II final rule became effective on Jan. 4, 2002, and can be viewed at: [www.hcfa.gov/medlearn/refphys.htm](http://www.hcfa.gov/medlearn/refphys.htm).

### Working With Consultants

The following article was taken from the Nov./Dec./Jan. 01-02 COLA Insights newsletter.

Laboratory consultants can be useful in dealing with problems involving communication, documentation and personnel. They can also be invaluable if you are setting up a new laboratory. Before hiring a consultant, identify the objectives or goals that you wish the consultant to meet. Being able to communicate your needs clearly to a candidate for your work will be the key to success. Once you have done this, interview several candidates. Find out experience, background, the types of laboratories they have worked in, etc. Be certain to check references. Legitimate references include current or previous clients, regulatory surveyors and previous employers. Ask for references that have had similar goals to your facility. Most importantly, you should be comfortable with your consultant. When you work with a new consultant on developing a contract, make sure the contract meets your needs. The contract should include what services will be performed, deadlines, deliverables and an agreed upon price for all services. In addition, the contract should state that any additional expenses must be approved prior to performance or they will not be paid. Keep track of all consultant time

and be sure to communicate the importance of your budget. Regular meetings and communication are imperative to a good working relationship.

### New CMS Website

The Centers for Medicare and Medicaid Services (CMS) new website is at [www.cms.hhs.gov](http://www.cms.hhs.gov). As the new website is developed, a large number of sites will link back to [www.hcfa.gov](http://www.hcfa.gov). Currently, CLIA-related information is located at: [www.hcfa.gov/medicaid/clia/cliahome.htm](http://www.hcfa.gov/medicaid/clia/cliahome.htm).

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Southeast Medical Center is looking for laboratories that have a F-series Sysmex hematology analyzer and are using the eight check controls. Contact Gail Scheffert or Judy Loepp, Southeast Medical Center, at 701.742.3267.

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